REMARKS

Claims 98-150 are pending in the present application. By this amendment, claims 102, 117, 119, 120, 123, 126, 136, and 137 have been amended. Accordingly, claims 98-150 are currently under consideration. Applicant respectfully submits that these claims are allowable.

Amendments to the Specification

The specification has been amended at paragraph [0048] so that the number of individuals or values of k in the sample is simply "K", which is the designation given in paragraph [0050]. Additionally, other amendments have been made to correct for inconsistencies (e.g, (lower-case) j takes on seven values when (upper-case) J=6). "[I]nformation contained in any one of the specification, claims or drawings of the application as filed may be added to any other part of the application without introducing new matter." (MPEP § 2163.06)

Objections to the Drawings

The drawing correction to Figure 2 stands objected to for not being sufficiently legible. Replacement drawing sheets are submitted herewith. Applicant respectfully requests that the above-cited objection be withdrawn.

Objections to the Claims

Claims 119 and 136 stand objected to for lacking a period. Appropriate amendments have been made. Applicant respectfully requests that the above-cite objection be withdrawn.

Claim Rejections Under 35 USC § 101

Claims 98-150 stand rejected under 35 USC § 101 for failing to provide a concrete, useful and tangible result.

Applicant respectfully traverses this rejection.

Applicant respectfully calls attention to the recent case *Ex Parte Lundgren* (76 USPQ2D 1385): As stated by the Board of Patent Appeals and Interferences, "there is currently no judicially recognized separate 'technological arts' test to determine patent eligible subject matter under § 101. We decline to create one." (76 USPQ2D 1385, at 1388). Further, as noted by the Board, "the Federal Circuit has held that a process claim that applies a mathematical algorithm to 'produce a useful, concrete, tangible result without preempting other uses of the mathematical principle, on its face comfortably falls within the scope of § 101. (citations to AT&T Corp. v. Excel Communications, Inc.)" (76 USPQ2D 1385, at 1386) In the present case, the claims are directed to a concrete, useful and tangible result in that, for example, models of features can be used to generate predictive values of the features (e.g., *"occlusion of a coronary artery"* in claim 112 as one specific example). Clearly, the claims of the present invention do not preempt other uses of the mathematical principle.

With respect to claims 117-133, these claims have been amended to further specify the structure of the claimed apparatus by reciting *"a computer."*

Applicant respectfully requests that the above-cited rejection under 35 USC § 101 be withdrawn.

Claim Rejections Under 35 USC § 112

Claims 98-150 stand rejected under 35 U.S.C § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Applicant respectfully traverses this rejection.

The Examiner has the burden to show a lack of enablement (MPEP 2164.04) This requires analysis of factors related to "undue experimentation", where "[i]t is improper to conclude that a disclosure is not enabling based on an analysis of only one the above factors while ignoring

one or more of the others." (MPEP 2164.01(a)) In particular, the MPEP lists eight factors (labeled (A)-(H)) that should be included in the analysis. (MPEP 2164.01(a)) With respect to the above-cited rejection, this burden has not been satisfied.

According to the Office Action, "the total 'Number in Bin' in each of FIGS. 3-9A is greater than 123." Applicant has amended the specification in paragraph [0048] so that "K trajectories are selected" without specifying the specific number, which can be estimated from FIGS. 3-9A. As will be readily appreciated by those skilled in the pertinent art of computer simulation, two points should be noted. First, the precise number of trajectories is not important for the purposes of the example. Secondly, plotting routines often introduce rounding errors so that the total number for the bins in each figure may not be precisely the same. The Office Action presents no argument why this typographical detail would lead to undue experimentation.

According to the Office Action, claims 111-113, 129-131 and 146-148 recite the limitation "hybrid functions" but "the convergence of the hybrid function" is not guaranteed. As will be readily appreciated by those skilled in the pertinent art of computer simulation, three points should be noted. First, in general, convergence is a theoretical justification based on an idealized limiting case that is not carried out in practice (e.g., $J \rightarrow \infty$). Secondly, a useful method need not possess a corresponding theoretical convergence result. And thirdly and a theoretical convergence result does not guarantee that a corresponding method will be useful in a practical sense. In this case, the Office Action appears to require a theoretical justification for the invention. However, A justifying theory is not necessary for an invention. The test of enablement relates to whether one skilled in the pertinent art is enabled "to make and use the invention." (MPEP 2164.01)

Applicant submits that the disclosure "is sufficient to permit those skilled in the art to make and use the invention." (MPEP 2164) In this context, one should note that "the amount of guidance or direction needed to enable the invention is inversely related to the amount of knowledge in the state of the art as well as the predictability of the art." (MPEP 2164.03) "A single embodiment may provide broad enablement in cases involving predictable factors, such as mechanical or electrical elements. (citations)" (MPEP 2164.03)

Applicant respectfully requests that the above-cited rejection under 35 USC § 112, first paragraph, be withdrawn.

Claims 7 (*sic*), 120, and 130 stand rejected under 35 U.S.C § 112, first paragraph, as failing to comply with the written description requirement. According to the Office Action, "'bin values' do not appear to have support in the original disclosure unless bin values equate bin ranges." Claims 102, 120, and claim 130 have been amended to refer to *"bin ranges."*

Applicant respectfully requests that the above-cited rejection under 35 USC § 112, first paragraph, be withdrawn.

Claim Rejections Under 35 USC § 102

Claims 98-100, 105, 107-111, 114, 116-118, 123, 125-129, 133-135, 140, 142-146, and 150 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Newman, "Model Reduction via the Karhunen-Loeve Expansion Part I: An Exposition", Institute for Systems Research and Electrical Engineering Department, University of Maryland, April 1996, pages 1-19 (IDS A, June 27, 2003).

Applicant respectfully traverses this rejection.

"A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." (MPEP § 2131)

With respect to claim 98, Newman does not disclose *"determining a plurality of sample data sets corresponding to the subjects in the subject group"* where there is *"a feature common to subjects in a subject group."* The mere collection of data (e.g., obtain empirical data, p. 17, par. 1) does not disclose these limitations.

Likewise, Newman does not disclose *"determining, from the sample data sets, a plurality of values for one or more mathematical parameters corresponding to one or more basis*

functions for the continuous mathematical model." The Office Action's reference to "obtain empirical data" relates to "empirically determined eigenfunctions." (p. 17, par. 1) However, the determination of *"values for one or more mathematical parameters corresponding to one or more basis functions"* is not covered by this disclosure. An analytical characterization of the coefficients $a_n(t)$ is presented, but the disclosure of "obtain empirical data" relates to the "empirically determined eigenfunctions." (p. 17, par. 1)

Likewise, Newman does not disclose *"determining, from the values for the one or more mathematical parameters, one or more distribution-function parameters for specifying one or more distribution functions for the one or more mathematical parameters."* The mere fact that the $a_n(t)$ are Fourier coefficients (p. 8, par. 3) does not disclose *"one or more distribution-function parameters for specifying one or more distribution functions."*

In summary, Newman does not disclose the limitations of claim 98. The Office Action appears to simply extrapolate from the equations at page 17, line 6, and page 8, line 11, without adequate support in the cited reference.

Applicant respectfully submits that the Examiner has improperly relied upon inherency in support of the rejection of claims under 35 U.S.C. § 102(b). Reliance on inherency when the reference is silent about the asserted inherent characteristic requires a rationale or evidence showing inherency. MPEP § 2112. The rationale or evidence "must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. Inherency, however, may not be established by probabilities or possibilities." In re Robertson, 169 F.3d 743, 745 (Fed. Cir. 1999) (citations omitted); MPEP §§ 2112, 2131.01.

The above-cited characteristic features of the present invention are not disclosed or suggested by the cited reference. Therefore, claim 98 is allowable over the cited reference. Because they depend directly or indirectly from claim 98 claims 99-116 are likewise allowable over

the cited reference. Furthermore, these claims recite limitations further from claim 98 and are independently patentable.

With respect to claim 99, Newman does not disclose *"receiving the sample data sets from an external data source and storing the sample data sets in a computer memory."* The mere disclosure of "obtain empirical data via experiment" (p. 17, par. 1) does not disclose this limitation. In particular, Newman does not disclose *"a computer memory."* Similarly, with respect to claim 100, Newman does not disclose *"measuring values for the feature and storing the values for the feature in the external data source."*

With respect to claim 105, Newman does not disclose *"simulating the feature by generating sampled values of the distribution functions by computer."* As discussed above, Newman simply does not disclose *"one or more distribution-function parameters for specifying one or more distribution functions for the one or more mathematical parameters."* Likewise, Newman does not disclose *"simulating the feature by generating sampled values of the distribution functions by computer."* The Office Action simply cites an equation (page 17, line 6) for this limitation. Likewise, Newman does not disclose *"displaying at least one statistical property of the simulated feature."* For this the Office Action simply cites a stochastic process having a zero mean (page 3, line 18).

With respect to claim 107, Newman does not disclose *"values for the features other than the first feature and values for the one or more distribution-function parameters specify the one or more distribution functions for the one or more mathematical parameters."* Simply disclosing that "the quantity of interest could be mass, energy or momentum" (p. 2, par. 5) does not disclose this limitation, which interrelates aspects of the claimed invention.

With respect to claim 108, Newman does not disclose *"simulating the first feature by computer, for given values of the features other than the first feature, by generating sampled values of the one or more distribution functions."* The Office Action cites only a mathematical formula. (p. 17, line 6) Newman simply does not disclose *"simulating ... by computer"* as claimed.

Similarly, Newman does not disclose *"displaying at least one statistical property of the simulated first feature."* Again a mathematical formula is cited in isolation. (page 3, line 18)

With respect to claim 109, Newman does not disclose *"a single basis function."* The disclosure of Newman is directed towards a general expansion and does not suggest cases where the number of terms is minimal (i.e., N=1) because of a specially chosen basis function as in certain embodiments of the present invention. "A genus does not always anticipate a claim to a species within the genus." (MPEP 2131.02)

With respect to claim 111, Newman does not disclose that *"the one or more basis functions include one or more hybrid functions that characterize features common to the subject group over a continuous interval."* The Office Action merely cites a function $v(x,t)$ (page 18, line 8) that is <u>not used as a basis function</u> in Newman.

With respect to claim 1114, Newman does not disclose that *"a computer determines the values for the one or more mathematical parameters and the one or more distribution-function parameters."* The Office Action merely cites "solving the differential equation to get a." (page 18, lines 3-4) There is no disclosure for how a *"computer determines the values."*

With respect to claim 116, Newman does not disclose that *"at least one normal distribution function and the one or more distribution-function parameters include at least one corresponding standard-deviation parameter."* The Office Action merely cites "introduce a probabilistic structure on the ensemble." (page. 3, lines 1-3)

As discussed in greater detail above with reference to claim 98, Applicant respectfully submits that the Examiner has improperly relied upon inherency in support of the rejection of claims under 35 U.S.C. § 102(b).

Similar arguments apply to the corresponding apparatus claims and computer-readable medium claims as cited in paragraphs 11-12 and 11-13 of the Office Action. Applicant respectfully requests that the above-cited rejection under 35 U.S.C. § 102(b) be withdrawn.

Applicant submits that these claims are distinguishable over the cited references and all references of record.

Claim Rejections Under 35 USC § 103

Claims 101, 112, 115, 119, 130, 132, 136, 147, and 149 stand rejected under 35 U.S.C. § 103(a) as unpatentable over Newman, "Model Reduction via the Karhunen-Loeve Expansion Part I: An Exposition", Institute for Systems Research and Electrical Engineering Department, University of Maryland, April 1996, pages 1-19 (IDS A, June 27, 2003) in view of Brown (U.S. Patent No. 5,956,501 issued September 21, 1999, (IDS C, December 19, 2001)).

Applicant respectfully traverses this rejection.

"To establish a prima facie case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to on of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations." (MPEP § 2143)

Applicant respectfully submits that that the Office Action has failed to present a *prima facie* case of obviousness.

As motivation combine the references, the Office Action states that "Brown's disease simulation system would benefit from Newman's model reduction via the K-L expansion at least for blood flow." (par. 13-1) This raises a number issues.

"The prior art can be modified or combined to reject claims as *prima facie* obvious as long as there is a reasonable expectation of success." (In re Merck & Co., Inc., 800 F.2d 1091) (MPEP 2143.02) However, it is not at all clear how to modify Brown's discrete-time system (e.g, col. 2, line 48) with Newman's K-L expansion (e.g., page 9, section 3.3) as proposed by the Office

Action. Applicant respectfully requests that a more complete explanation of the proposed combination be provided together with a corresponding motivation. "The mere fact that references can be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination." (MPEP 2143.01)

"It is improper to combine references where the references teach away from their combination." (*In re Grasselli*, 713 F.2d 731, 743) (MPEP 2145) In this case, Newman is directed towards "formulating suitable mathematical models for a particular physical system. For a dynamical system in continuous time, the model is often some system of ordinary differential equations or partial differential equations." (p. 1, Introduction, line 2) For example, the Office Action cites equations on page 17 of Newman where the underlying model is a partial differential equation (PDE). (page 16, Section 3.6, equation 32) By contrast, Brown's disclosure is directed towards "a disease simulation system which is sufficiently accurate to teach a patient appropriate self-care actions and sufficiently simple to be understood by the average patent." (col. 2, line 17) Brown proposes discrete-time systems (e.g, col. 2, line 48), and contrasts this approach with more complex models involving differential equations. "Each mathematical compartmental model uses partial differential equations and calculus to simulate a psychological process. This compartmental modeling approach has several disadvantages. First, understanding the compartmental models requires advanced mathematical knowledge of partial differential equations and calculus which is far beyond the comprehension level of a typical patient. Consequently, each model is an unfathomable 'black box' to the patient who must nevertheless trust the model and rely on upon it to learn critical health issues." (col. 1 lines 54-64) That is, Brown teaches away from using the differential or continuous-time mathematical models disclosed by Newman. In this way Brown teaches away from a combination with Newman as proposed by the Office Action.

In summary, it is not clear how to achieve or to motivate a combination of Newman and Brown as proposed by the Office Action. "The references must be considered as a whole and must suggest the desirability and thus the obviousness of making the combination." (MPEP 2141)

"To establish a *prima facie* case of obviousness of a claimed invention, all the claim limitations "must be taught or suggested by the prior art." (*In re Royka*, 490 F.2d 981) (MPEP § 2143.03)

With respect to claim 112, Brown does not disclose *"a model for occlusion of a coronary artery over the continuous interval."* The Office Action cites col. 1, lines 15-20, and col. 2, lines 17-25, but this disclosure appears to relate to disease control parameters that can be monitored (e.g., by a patient).

Applicant respectfully submits that the Examiner has improperly relied upon inherency in support of the rejection of claims under 35 U.S.C. § 103(a). Reliance on inherency when the reference is silent about the asserted inherent characteristic requires a rationale or evidence showing inherency. MPEP § 2112. The rationale or evidence "must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. Inherency, however, may not be established by probabilities or possibilities." In re Robertson, 169 F.3d 743, 745 (Fed. Cir. 1999) (citations omitted); MPEP §§ 2112, 2131.01.

Similar arguments apply to the corresponding apparatus claims and computer-readable medium claims as cited in paragraphs 13-2 and 13-3 of the Office Action. Applicant respectfully requests that the above-cited rejection under 35 U.S.C. § 103(a) be withdrawn.

Applicant submits that these claims are distinguishable over the cited references and all references of record.

Claims 102-204, 106, 120-122, 124, 137-139, and 141 stand rejected under 35 U.S.C. § 103(a) (35 U.S.C. § 102(b), *sic*) as unpatentable over Newman, "Model Reduction via the Karhunen-Loeve Expansion Part I: An Exposition", Institute for Systems Research and Electrical Engineering Department, University of Maryland, April 1996, pages 1-19 (IDS A, June 27, 2003) in view Applicants' assertions.

Applicant respectfully traverses this rejection.

"To establish a prima facie case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to on of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations." (MPEP § 2143)

Applicant respectfully submits that that the Office Action has failed to present a *prima facie* case of obviousness.

"The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on the applicant's disclosure." (MPEP § 2143) The Office Action has improperly made reference to the applicant's disclosure for "The teaching or suggestion to make the claimed combination and the reasonable expectation of success."

"To establish a *prima facie* case of obviousness of a claimed invention, all the claim limitations "must be taught or suggested by the prior art." (*In re Royka*, 490 F.2d 981) (MPEP § 2143.03)

With respect to claim 102, Newman does not disclose *"determining initial values for the one or more mathematical parameters according to an optimization criterion; separating the initial values into bins with corresponding bin ranges; and determining the values for the one or more mathematical parameters by replacing the initial values with the bins. "* The Office Action merely cites a portion of paragraph [00028] that discusses related knowledge of those skilled in the art. The Office Action provides no reference to the specific limitations "because the detail steps are well known and need no further teachings." (par. 14-1)

With respect to claim 103, Newman does not disclose *"calculating the values for the one or more mathematical parameters from the sample data sets according to an optimization criterion."* The Office Action merely cites a portion of paragraph [00040] that discusses related knowledge of those skilled in the art. The Office Action provides no reference to the specific limitations "because the detail steps are well known and need no further teachings." (par. 14-2)

With respect to claim 104, Newman does not disclose *"calculating the one or more distribution-function parameters from the values for the one or more mathematical parameters according to an optimization criterion."* The Office Action merely cites a portion of paragraph [00072] that discusses related knowledge of those skilled in the art. The Office Action provides no reference to the specific limitations "because the detail steps are well known and need no further teachings." (par. 14-3)

With respect to claim 106, Newman does not disclose *"selecting a plurality of initial basis functions; determining a plurality of values for a plurality of mathematical parameters corresponding to the initial basis functions; determining, from the values for the mathematical parameters corresponding to the initial basis functions, a correlation matrix for the initial basis functions; and determining, from the correlation matrix, the one or more basis functions according to a de-correlation criterion."* The Office Action merely cites a portion of paragraph [00056] that discusses related knowledge of those skilled in the art. The Office Action provides no reference to the specific limitations "because the detail steps are well known and need no further teachings." (par. 14-4)

Applicant respectfully submits that the Examiner has improperly relied upon inherency in support of the rejection of claims under 35 U.S.C. § 103(a). Reliance on inherency when the reference is silent about the asserted inherent characteristic requires a rationale or evidence showing inherency. MPEP § 2112. The rationale or evidence "must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. Inherency, however, may not be established by

probabilities or possibilities." In re Robertson, 169 F.3d 743, 745 (Fed. Cir. 1999) (citations omitted); MPEP §§ 2112, 2131.01.

Similar arguments apply to the corresponding apparatus claims and computer-readable medium claims as cited in paragraphs 14-5 and 14-6 of the Office Action. Applicant respectfully requests that the above-cited rejection under 35 U.S.C. § 103(a) be withdrawn.

Applicant submits that these claims are distinguishable over the cited references and all references of record.

CONCLUSION

In view of the above, each of the presently pending claims in this application is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejection of the claims and to pass this application to issue. If it is determined that a telephone conference would expedite the prosecution of this application, the Examiner is invited to telephone the undersigned at the number given below.

In the event the U.S. Patent and Trademark office determines that an extension and/or other relief is required, applicant petitions for any required relief including extensions of time and authorizes the Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to Deposit Account No. **03-1952** referencing docket no. **071882000200**. However, the Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

Dated: December 30, 2005

Respectfully submitted,
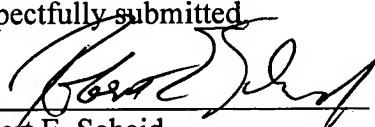
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